# PostScript

## LETTERS

### Edgar Schoen does not represent the North American view of male circumcision

We dispute the claim that Schoen represents the North American view.[1] We think that he represents only his personal view and that of a few disciples.

Schoen's claims have been rejected wherever he goes. When he published in the *New England Journal of Medicine* in 1990,[2] his views were opposed by Poland.[3] When he published in *Acta Paediatrica Scandinavia* in 1991,[4] his views were rebutted by Bollgren and Winberg.[5] When Schoen published in this journal in 1997,[6] his views were countered by Hitchcock[7] and also by Nicoll.[8] In the present instance, his views are offset by Malone.[9]

When the Canadian Paediatric Society published their position statement on neonatal circumcision in 1996,[10] they followed the views of Poland,[3] not those of Schoen.[2] Although Schoen was chairman of the American Academy of Pediatrics (AAP) taskforce on circumcision that published in 1989,[11] he did not serve on the AAP taskforce on circumcision that published in 1999.[12] That second taskforce distanced the AAP from the views published by Schoen's taskforce[11] a decade earlier.

Schoen's present views on circumcision are strikingly similar to those of Wolbarst,[13] which were published nearly a century ago. This suggests that Schoen's views are founded in a desire to preserve his culture of origin, not in medical science. Goldman writes:

> ''One reason that flawed studies are published is that science is affected by cultural values. A principal method of preserving cultural values is to disguise them as truths that are based on scientific research. This 'research' can then be used to support questionable and harmful cultural values such as circumcision. This explains the claimed medical 'benefits' of circumcision.''[14]

The present North American view is that neonatal circumcision is not of medical value and that any benefits are more than offset by the risks, complications, and disadvantages of non-therapeutic infant circumcision. The Canadian Paediatric Society states: ''Circumcision of the newborn should not be routinely performed''.[10] The American Academy of Family Physicians described neonatal circumcision as ''cosmetic'' in nature.[15] More recently, the College of Physicians and Surgeons of British Columbia reported:

> ''Infant male circumcision was once considered a preventive health measure and was therefore adopted extensively in Western countries. Current understanding of the benefits, risks and potential harm of this procedure, however, no longer supports this practice for prophylactic health benefit. Routine infant male circumcision performed on a healthy infant is now considered a non-therapeutic and medically unnecessary intervention.''[16]

A recent North American cost-utility study concluded:

> ''Neonatal circumcision is not good health policy, and support for it as a medical procedure cannot be justified financially or medically.''[17]

The statistics provided by Schoen on the incidence of circumcision in North America are out of date. The popularity of non-therapeutic infant circumcision is declining. The Association for Genital Integrity reports that only 13.9% of male infants in Canada were circumcised in 2003.[18] Data provided by the National Hospital Discharge Survey indicate that the percentage of male infants circumcised in the United States declined to 55.1% in 2003.[19] One expects to see further declines in the popularity of circumcision as newer data are reported. Many health maintenance organisations in the USA and most Canadian health insurance plans no longer pay for non-therapeutic circumcision of infant boys.

With regard to prevention of urinary tract infection (UTI), the only North American recommendation we can find is that of the Section on Breastfeeding of the AAP, which recommends breast feeding to reduce the incidence of UTI in all infants.[20] It says that procedures that ''may traumatize the infant'' or otherwise interfere with breast feeding initiation should be avoided.[20] Circumcision, a highly traumatic procedure, which apparently produces an ''infant analogue of post-traumatic stress disorder'',[21] works against breast feeding initiation and ultimately against optimum child health and development as well as establishment of UTI protection by breast feeding.[22] The most recent AAP task force on circumcision does not recommend circumcision to prevent UTI or for any other reason.[12]

Both parents and healthcare providers have a general duty to consider the ''best interests'' of the whole child.[23] This must include sexual and psychological wellbeing[24] and the child's interest in preserving his legal right to bodily integrity.[25] Most discussions of the alleged value of circumcision in preventing UTI usually take an excessively narrow view.

One should not characterise Schoen's personal view as representing the North American view. North America has moved on.

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## Trial registration, the ICMJE statement, and paediatric journals

The risk of wide unnecessary duplication (as opposed to necessary replication) in research, including paediatric research,[1] is high. Furthermore, the risk of research findings disappearing from the public knowledge base is especially high for negative trials. Prospective registration of clinical trials should reduce such inadequacies, promote collaboration, facilitate disclosure of information to the public and those involved in health care, and reduce waste of effort and resources.[2]

The issue has been widely debated in the biomedical journals and many groups have begun to discuss their role in such a matter. In September 2004, the International Committee of Medical Journal Editors (ICMJE), representing 11 different medical journals (plus the *British Medical Journal* which also joined the initiative), published a statement specifying their intent to require, as a condition of consideration for publication, registration of trials in a public trials registry at onset of patient enrolment.[3] Trials starting recruitment after 1 July 2005 will now be considered for publication in the 12 journals only if they have registered by that date. Trials beginning enrolment before then must have registered by 13 September.

It is important that all knowledge gained from trials concerning populations with an evident lack of evidence based knowledge, such as children (who are at a disadvantage compared to adults with respect to optimal drug therapy), be made publicly available. Trial registration should contribute to closing the gap. Patients (and their parents) who volunteer to participate in trials deserve to know that their contributions will inform future healthcare decisions.

In such a context, although the issue for paediatrics was settled without success 15 years ago,[4] we would like to point out that none of the journals that have participated in the discussion on trial registration are paediatric journals. We feel it is fundamental that children be kept well in mind when discussing such an issue and feel that paediatric journals should therefore participate actively in the matter.

A European register of clinical trials on drug therapy in children (www.dec-net.org) has been running since mid 2004, supported by the European Union under its Fifth Framework Programme, Thematic Programme ''Quality of Life'' (contract QLG4-CT-2002-01054). At present, DEC-net (in addition to www.clinicaltrials.gov, the US National Library of Medicine's register) is the only one fitting the ICMJE's criteria, which state that a register must be freely accessible to the public; open to all prospective registrants; managed by a non-profit organisation; electronically searchable; contain validated data, and include a set of minimal data (a unique ID number, the study interventions, hypothesis, primary and secondary outcome measures, eligibility criteria, key trial dates, target number of subjects, funding source, and contact information for the principal investigator).

Trial registration has become a public issue: the World Health Organisation supports initiatives devoted to disclosing standard information[5] on ongoing clinical trials, and governments around the world are beginning to make trial disclosure mandatory.

We would like to ask paediatric journals to make their positions on trial registration known and would like to reiterate the important role that a register such as DEC-net can have in the matter.

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## Gaviscon for gastro-oesophageal reflux in infants: a poorly effective treatment?

We read with interest the recent article by Del Buono *et al* evaluating the effect of sodium and magnesium alginate (Gaviscon) on gastro-oesophageal reflux (GOR) in infants.[1] It provides an objective assessment of the effects of a drug widely used in the treatment of paediatric GOR by means of a double blind drug versus placebo trial, in which the effects of each treatment were evaluated by means of the simultaneous application of multichannel intraluminal impedance and pH-metry (MII/pH). The authors show that Gaviscon reduces this height, probably because it increases the viscosity of the gastric content and hence acts in the same way as thickened feeding.[2] They also found that fewer acid reflux episodes occurred after Gaviscon, though the difference was not significant. By contrast with the evidence produced in other studies,[3] therefore, these results seem to suggest that Gaviscon Infant has little effect on GOR when assessed in objective terms. It is, however, possible that the significance of some of the differences they observed has been weakened by the influence of sleep and wakefulness on GOR episodes.[4]

During 53 MII/pH 24 h monitorings in infants with GOR symptoms at our centre, we noted a significant difference between the number of episodes during wakefulness (535 hours) and sleep (450 hours): $3.2 \pm 4.1$ episodes per hour versus $1.8 \pm 3.3$ ($p < 0.001$; CI $0.93 \pm 1.87$). Del Buono *et al* gave six milk meals plus drug or placebo according to a 3+3 schedule. If we suppose that a infant sleeps 12 hours a day, then the probability that ''sleep'' and ''wakefulness'' periods were equally distributed between Gaviscon and placebo in each of their 20 patients can be no more than 50%. This probability drops even further if account is taken of the fact that infants with GOR sleep less than normal. The difference in GOR frequency between sleep and wakefulness, coupled with the asymmetrical distribution of these phases, constitutes a ''confounding factor'' responsible for great variability of all the frequency data (number of episodes per hour, number of acid episodes, number of postprandial episodes per hour, etc), whereas it may have little influence on GOR ''quality'' (duration, pH, and height).

We thus believe that assessment of efficacy of the treatment of GOR by means of MII/pH requires longer observation periods (for example, 24 h placebo versus 24 h drug), or at all events consideration of the influence of sleep and wakefulness on GOR episodes.

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